Complete Summary

GUIDELINE TITLE

Hysteroscopic surgery. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Hysteroscopic surgery. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1999. 19 p. (SIGN publication; no. 37). [60 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Menorrhagia

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present evidence-based recommendations for hysteroscopic surgery

TARGET POPULATION

Women with menorrhagia

INTERVENTIONS AND PRACTICES CONSIDERED

Patient Selection for Hysteroscopic Surgery

1. Evaluation of indications and contraindications for endometrial resection or ablation; use of patient selection checklist
2. Preoperative hysteroscopy
3. Endometrial sampling
4. Patient counseling on relative benefits and risks of surgery; use of patient information leaflet

Hysteroscopic Surgery

1. Transcervical endometrial resection with loop diathermy electrode using video camera equipment and good irrigation
2. Endometrial ablation using rollerball ablation or laser ablation (neodymium-yttrium-aluminum-garnet [Nd:YAG] laser at no less than 80W power)
3. Endometrial preparation using gonadotrophin-releasing hormone (GnRH) analogues or danazol or their combination
4. Training of surgeons in hysteroscopy skills
5. Serial measurement of haemoglobin, haematocrit, and serum sodium during surgery to monitor for signs of irrigation fluid overload
6. Management of uterine perforation -- maintenance of haemostasis
7. Postoperative care, including recording or vital signs, vaginal loss, pain, orientation, and analgesia
8. Discharge planning, including patient information outlining postoperative advice

Note: Antibiotic prophylaxis and thromboembolism prophylaxis are considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Menstrual loss volumes
- Patient satisfaction rates
- Length of time to return to work and normal activities
- Length of hospital stay
- Postoperative morbidity

- Further surgery/hysterectomy rates
- Dysmenorrhoea and pre-menstrual syndrome (PMS) symptom rates
- Scores of anxiety and depression following surgery
- Bladder symptoms after surgery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with SIGN methodology. An initial systematic review of the literature was carried out using an explicit search strategy using the Cochrane Library, Embase (1988-1996), HealthStar (1985-1996), and Medline (1985- 1996). Information was also provided by the Scottish Health Purchasing Information Centre (SHPIC) and a hand search of the journal Gynaecological Endoscopy was carried out. This evidence base was updated to incorporate studies published during the course of development of the guideline.

Papers were only included if they adhered to recognisable methodological principles, including adequate sample size, a clearly identified hypothesis and measure of outcome, and accurate reporting of results. Whenever possible randomised trials have been discussed. However, due to the paucity of sound randomised controlled trials work in this area, the literature search was extended to cover all types of study and a number of clinical studies have been included.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developer's Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record

and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

Grades of Recommendations

Grade A: Requires at least one randomized controlled trial (RCT) as part of a body of literature of overall good quality and consistency addressing the specific recommendation (Evidence levels Ia, Ib).

Grade B: Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation (Evidence levels IIa, IIb, III).

Grade C: Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV).

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

Although many studies have been carried out comparing hysterectomy with transcervical resection of the endometrium/endometrial laser ablation (TCRE/ELA), very few have been prospective randomised studies and hardly any have considered the cost implications.

To determine the cost effectiveness of hysteroscopic surgery compared with hysterectomy for dysfunctional uterine bleeding it is necessary to know not only comparative costs of the operation but also the costs and benefits of short and long term follow-up, subsequent hysterectomy rates and patient satisfaction. Two randomised studies from Bristol and Aberdeen meet the required criteria. In Bristol, a prospective economic evaluation running alongside a randomised controlled trial reported that, on the basis of health service resource cost input four months after surgery, with transcervical resection of the endometrium has a cost advantage over abdominal hysterectomy. These results were supported by a further study which reviewed the health related quality of life and costs two years after surgery. Similar results were found in the economic evaluation of the randomised trial of hysterectomy and transcervical resection of the endometrium/endometrial laser ablation from Aberdeen.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

1. National open meeting discusses the draft recommendations of each guideline.
2. Independent expert referees review the guideline.
3. The Scottish Intercollegiate Guidelines Network (SIGN) Editorial Board reviews the guideline and summary of peer reviewers' comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document:

The strength of recommendation grading (A-C) and level of evidence (Ia-IV) are defined at the end of the "Major Recommendations" field.

Patient Selection For Hysteroscopic Surgery

A - Hysteroscopic surgery - transcervical resection of the endometrium (TCRE) or endometrial laser ablation (ELA) - should be offered as an option to all women needing surgical management of dysfunctional uterine bleeding.

A - The main indication for hysteroscopic surgery is dysfunctional uterine bleeding in a woman who has completed her family in whom surgical treatment is indicated.

A - Pre-menstrual pelvic pain not related to excessive bleeding is a relative contraindication.

C - Counselling is vitally important both to ensure that the patient understands the implications of the procedure and for medico-legal reasons. A patient information leaflet is recommended.

B - The uterus should be less than 12 weeks in size and the endometrium should be histologically normal.

B - Endometrial sampling is essential prior to hysteroscopic surgery.

A - Preoperative hysteroscopy is not needed in the majority of women whose uterus is not enlarged.

Methods of Hysteroscopic Surgery

Transcervical Endometrial Resection

B - Loop resection of the cornua should be avoided and endometrial destruction with a rollerball electrode is advised.

C - All methods should be carried out using video camera equipment to maximise the view.

C - Good irrigation will clear blood and debris rapidly from the field of vision and maintain uterine distension.

C - Orientation is essential and is best achieved by identifying both tubal ostia and observing air bubbles on the roof of the cavity.

Endometrial Ablation

B - The laser power with the neodymium:yttrium-aluminum-garnet (Nd:YAG) laser should be no less than 80 W.

C - The laser must not be activated when stationary.

Endometrial Preparation

B - Endometrial preparation is recommended.

A - Either a gonadotrophin releasing hormone (GnRH) analogue or danazol may be used: a gonadotrophin releasing hormone analogue may give better results, compliance is more certain and will reduce the size of fibroids.

C - In patients in whom a difficult cervical dilatation is anticipated danazol may be preferred.

C - Obese women pose a problem as gonadotrophin releasing hormone analogues alone give poor thinning: a combination of both agents may be the most effective.

Minimisation of Complications and Risks

C - The risks associated with hysteroscopic surgery can be minimised by experienced operators and hence training and supervision for those less experienced is imperative.

Uterine Perforation

C - If uterine perforation is suspected while activating the resectoscope or laser, immediate laparoscopy is indicated.

C - If perforation is confirmed and associated with active diathermy, laparotomy may be required if there is any suspicion of bowel or vascular damage.

Irrigation Fluid Absorption

A - Laser ablation leads to greater fluid absorption than endometrial resection.

C - The operator must be constantly aware of the fluid volume infused and the volume removed. The assisting staff should make a formal report of this balance at five minute intervals.

B - An accurate assessment of the calculated deficit must be made.

B - If the deficit exceeds 1500 mL then the procedure should be abandoned unless it is nearly complete.

C - Haemoglobin, haematocrit and serum sodium must be measured serially and the patient observed postoperatively for signs of fluid overload. If a rapid deficit occurs during a procedure, uterine perforation must be suspected.

Haemostasis

B - In the rare event that significant bleeding persists, a 30 mL balloon Foley catheter (14 to 18 gauge) can be inserted in to the uterine cavity and inflated to effect tamponade. The catheter should be left in situ for 12 hours before removal.

Definitions

Grades of Recommendations:

A. Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B. Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)
C. Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Statements of Evidence

Ia
Evidence obtained from meta-analysis of randomized controlled trials.

Ib
Evidence obtained from at least one randomized controlled trial.

IIa
Evidence obtained from at least one well-designed controlled study without randomization.

IIb
Evidence obtained from at least one other type of well-designed quasi-experimental study.

III
Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV
Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

In general, endometrial resection/ablation offers patients satisfaction only slightly less than hysterectomy but with significantly less morbidity and faster recovery.

Specific benefits include the following:

- Reduction of menstrual blood loss
- High levels of patient satisfaction
    - One-year follow up studies have shown hysteroscopic endometrial resection/ablation to result in patient satisfaction in about 84% of the cases, compared with 93% following hysterectomy
- Shorter time back to work and normal activities compared with hysterectomy
- Decreased hospital stay compared with hysterectomy
- Less postoperative morbidity
    - Two large randomised trials comparing hysteroscopic surgery with abdominal hysterectomy for the management of menstrual dysfunction concluded that postoperative morbidity was significantly less following transcervical endometrial resection/endometrial ablation compared with hysterectomy
- Avoidance of further surgery/hysterectomy
- Dysmenorrhoea and pre-menstrual syndrome (PMS) symptoms and scores of anxiety and depression are improved following either transcervical endometrial resection or endometrial ablation

Subgroups Most Likely to Benefit:

The best results can be expected in women aged over 45 with proven menorrhagia due to dysfunctional bleeding, which is unresponsive to traditional drug treatment, and who are otherwise faced with hysterectomy.

POTENTIAL HARMS

Hysteroscopic Surgery, General Risks

- There is a small chance the procedure will need to be abandoned temporarily or permanently due to perforation (about 1% risk), fluid overload, problems dilating the cervix, or unexpected fibroids. Rarely, a hysterectomy will need to be carried out (reported rates vary widely and local rates should be discussed with the patient). Damage to other organs can occur but is very uncommon.

The main risks associated with hysteroscopic surgery appear to be uterine perforation, fluid overload and to a lesser extent haemorrhage and infection.

- Pregnancy is both possible and potentially hazardous to both mother and fetus after endometrial ablation, therefore the woman's family must be complete. Continued use of contraception is strongly advise and concurrent sterilisation should be offered at the time of ablation.
- Some women develop late onset pain with or without bleeding after 12 months.

Transcervical Endometrial Resection

- Deeper resection will increase the risk of uterine perforation, increase fluid absorption and cause excessive bleeding by disturbing larger vessels.

Endometrial Ablation -- Rollerball Ablation

- There is a very low reported incidence of complications relating to fluid overload in rollerball ablation. Perforation of the uterus with the rollerball is very unlikely to take place, but bowel perforation and fistula formation have been described where the uterus has undergone full thickness coagulative myometrial necrosis but without actual perforation.

Endometrial Ablation -- Laser Ablation

- There are significant risks of blindness caused to theatre staff and the patient if the laser rules are not strictly adhered to.

Subgroups Most Likely to be Harmed:

Failure has been found to be more common in women aged under 40, if surgeons had done less than 10 previous hysteroscopic endometrial ablations, if intramural fibroids were present, if performed during the luteal phase of menstrual cycle, or for certain methods of endometrial thinning.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve.

These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.

Significant departures from the national guideline as expressed in the local guideline should be fully documented and the reasons for the differences explained. Significant departures from the local guideline should be full documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Hysteroscopic surgery. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1999. 19 p. (SIGN publication; no. 37). [60 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Apr

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr David Parkin (Chairman); Dr Gillian McIlwaine; Mrs Marion McGhee; Dr Robert Chatfield; Dr Denny Philips; Dr Ian Duncan; Dr Jane Campbell; Mr Andrew Radley

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 1999 and will be considered for review in 2002.

Any updates to the guideline that result from the availability of new evidence will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Hysteroscopic surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 1999 Apr. 1 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 3, 2002. The information was verified by the guideline developer as of February 4, 2002.

COPYRIGHT STATEMENT

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